EPA's Use of Science

The science on Environmental Tobacco Smoke (ETS) is complicated. The methodology used by EPA for analyzing that science is controversial. The conclusions the EPA reached are not supported by that science.

Here are some basic points that must be understood:

The EPA reviewed 30 studies on lung cancer and ETS exposure, which were published by independent researchers around the world beginning in the early 1980s.

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The EPA conducted no original research.

Each of these studies is an epidemiological study. Put in the simplest possible terms, the results are mathematical or statistical calculations of disease risk based on responses to survey questionnaires, primarily by the nonsmoking spouses of smoking husbands. This is not clinical or laboratory research. In fact, the very few animal inhalation studies that have been done don't support the EPA's conclusion.

Such epidemiological work is, by its very nature, prone to a wide variety of errors, particularly if the study results are inconclusive or do not adequately address factors related to

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disease that could significantly alter the conclusions, such as diet, heredity or socioeconomic status.

Many of the ETS studies have these problems.

Of the 30 studies reviewed by the EPA, 24 originally reported risk estimates that did not reach overall statistical significance.

That means that the estimated risks reported in those 24 studies: may have arisen by chance alone, rather than demonstrate a possible relationship between ETS exposure and lung cancer; or those studies simply indicated no statistically significant increased cancer risk based on exposure to ETS.

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For its risk assessment on ETS and lung cancer, the EPA relied on 11 studies conducted in the United States. Of those, not one originally reported statistically significant results overall. It was only after the EPA went back and lowered the statistical standard used by the studies' authors, as originally published, that EPA was able to force the conclusion of increased risk.

In the statistical calculations for risk assessments, a calculated relative risk of "one" or lower indicates no increased risk. The mere fact that a risk is larger than one

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does not mean it reaches statistical significance; results still could have arisen by chance.

The relative risk number that EPA calculated for ETS is 1.19, indicating a weak association. It is very easy to see that even small inaccuracies in the studies or in the analysis of the studies could reduce the reported relative risk number to one -- meaning no increased risk.

The EPA achieved its 1.19 relative risk number for ETS by combining results of the 11 U.S. studies in a process called meta-analysis and by lowering the statistical standard used by the authors of the original studies. Meta-analysis is used to analyze a group of studies on the same subject. The application of meta-analysis is in and of itself an extremely controversial subject among scientists, particularly when it is attempted with studies that are conducted with widely varying methodologies and under widely varying circumstances, such as all of the studies on ETS.

When the EPA performed its meta-analysis, the EPA also re-calculated the data from the original studies. In doing so, the EPA reduced the accepted statistical standard for analysis and concluded that there is a statistically significant increased risk associated with exposure to ETS. While complicated, this is not an arcane point. It is fundamental because, given the original data, it was the only

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way EPA could come to its conclusion of increased risk.

A very important point that can be made about the risk of ETS is this: One of the largest and most recent studies on ETS was published in the November 1992 issue of the American Journal of Public Health.

It was conducted with funding from the National Cancer Institute. The study examined reported ETS exposures of nonsmoking women. Specifically examined were exposures of nonsmokers at home (from spouses and other family members), exposures at the workplace, and exposures during childhood.

That study reported no overall statistically significant association between ETS and lung cancer for any of those situations.

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That study is not included in the EPA risk assessment. If its data were included in the risk assessment and analyzed using accepted statistical standards, the overall lung cancer risk estimate from ETS exposure would not be statistically significant.

In fact, four of the five largest and most recent studies -- three conducted in the United States and one in China -- report no statistically significant increased risk of lung cancer from spousal smoking. The fifth is incomplete, and

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although the EPA relies heavily upon its results, much of the data required for final calculation have not yet been incorporated.

We do not expect anyone to challenge the EPA because someone from the tobacco industry says so. We sincerely hope, however, that someone will do so because the science, reviewed objectively, does not support the EPA conclusion.

Risk in Perspective

Even if one accepts the EPA conclusion at face value, the overall relative risk estimate is so low and, consequently, barely statistically significant, even when subjected to EPA's controversial methodology -- it is extremely important for the EPA claims to be taken in context.

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Statements about ETS Exposure

To quote Dr. Morton Lippmann, the Chairman of the EPA SAB committee which reviewed the EPA study, "the possibility of cancer from secondhand smoke is a small added risk, probably much less than you took to get here through Washington traffic." This is Dr. Lippmann's view, expressed at a news conference discussing the report.

In fact, a study published in the July issue of the American

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Journal of Public Health has concluded that drinking chlorinated water poses a significant risk of bladder and rectal cancer for humans. The risk calculated is greater than the EPA estimate for ETS exposure and lung cancer. The methodology used is essentially the same as used by EPA in the risk assessment on ETS. To quote Dr. Devra Lee Davis, scholar in residence at the National Research Council of the National Academy of Sciences, and known for her opposition to tobacco:

> Let me remind you that the relative risk we are talking about here [for chlorinated water] is higher than the relative risk for environmental tobacco smoke. The difference is that nobody likes environmental tobacco smoke. It's kind of easy. It's easy for people to say, "Oh, let's get rid of that smoke, it's really nasty and horrible," but, in fact, the relative risk we are talking about here in the highest exposed group in [Ken Cantor's] study was higher than the relative risk, for the average, for lung cancer for someone who married a smoker. Think about that.

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The real question that the EPA risk assessment on ETS poses to the American people is, "What does all this mean?"

We believe that when all the science is carefully and

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objectively analyzed, the scientific conclusion is: Based on all available scientific studies, exposure to Environmental Tobacco Smoke is not associated with an increased risk of lung cancer for nonsmokers.

Accommodation

Whatever the ultimate conclusions of science, those will not and cannot address the policy issue of ETS.

Smoking has become an issue of conflict in our society. Smoking in enclosed, poorly ventilated places can be annoying. It may be offensive -- to smokers as well as nonsmokers. But nearly one-third of American adults do smoke.

This society, which better than all others has been able to protect the rights of all, should certainly be able to find a way to do that for smokers and nonsmokers alike.

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We believe this can be accomplished through a two-pronged approach: 1) reasonable accommodation of nonsmokers and smokers alike; and 2) a focus on a broad-scale approach that addresses the numerous problems associated with indoor air quality.

For some, establishing separate smoking and nonsmoking areas, all with adequate ventilation -- in the workplace, in

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restaurants and in enclosed spaces -- can go a long way toward reducing the frictions that exist.

If we add to the mix a responsibility on the part of smokers to be courteous and on the part of nonsmokers to work toward reasonable accommodation, then the problem, the conflict, will be eased.

Everyone is concerned about indoor air quality, but the problem is the overall indoor air quality. Just look at the number of reports on "sick building syndrome." Many of the complaints indicate problems in office buildings, courthouses and schools where smoking is not permitted. In fact, a NIOSH study reported the majority of indoor air quality problems as attributable to poor ventilation, with only 2%-4% attributable to ETS.

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ETS and Childhood Respiratory Disease

Perhaps no claim regarding ETS is as capable of provoking strong feelings as those that relate to children. While the issue of parental smoking is laden with emotion, the scientific basis for the claim is difficult to interpret.

However, the EPA has so narrowly focused its review on ETS that it is not possible to determine whether ETS or a number of other agents are responsible for its conclusions. Molds, dust mites, humidity, exposure to adults and other children -- in the home, at school or in day care -- who may already be ill, as well as socioeconomic factors have all been strongly linked to respiratory illness in children. EPA was unable to isolate those confounding factors in its review, which raises significant questions as to any conclusions regarding the effects of exposure to ETS.

In addition, the EPA's claims were generated by a partial and selective review of the literature. The studies relied on by the EPA are inconclusive and inconsistent with others, at least 25 of which reported no statistically significant association and were not mentioned by EPA.

The growing number of complaints of childhood respiratory problems associated with poor indoor air quality in schools

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where ETS is not a factor should be a further indicator that something may be going on that is entirely unrelated to ETS.

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